Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0306320	02/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of Auburn	2901 Corporate Park Drive, Opelika, AL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to ensure the Laboratory Director signed the attestation statements for two of three events in 2022. The findings include: 1. A review of the API PT records revealed no signature by the Laboratory Director (or designee) on attestation statements for the following surveys: a) 2022 Hematology 1st Event. b) 2022 Hematology 3rd Event. 2. During an interview on February 28, 2022, at 9:43 AM, Testing Personnel #1 confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by:

	Based on a review of the refrigerator temperature records, the Cell Dyn 18+ Quality Control package insert, and an interview with Testing Personnel #1, the Laboratory failed to document temperatures for the refrigerator in which the Hematology QC was stored since the previous survey on 5/11/2021 to the current survey on 2/28/2023. The findings include: 1. A review of the temperature records revealed the laboratory failed to document temperatures for the refrigerator in which the Cell Dyn+ Hematology Controls were stored since the previous survey on 5/11/2021. 2. A further review of the Cell Dyn 18+ Control package insert reveals, "Cell Dyn 18+ controls should be tightly capped and stored at 2-10 degrees Celsius." 3. During an interview on February 28th, 2023, at 12:19 PM, Testing Personnel #1 confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Hematology maintenance records and an interview with Testing Personnel #1, the Laboratory failed to perform and document monthly maintenance on the Abbott Cell Dyn Emerald Hematology analyzer as per the manufacturer's requirements for 16 of 21 months reviewed from 2021 to 2023. The findings include: 1. A review of the Abbott Cell Dyn Emerald Hematology analyzer records revealed no documentation of monthly maintenance in: a) 2021: July, August, October through December b) 2022: February, March, May through December c) 2023: January 2. During an interview on February 28, 2023, at 12:45 AM, Testing Personnel #1 confirmed the above findings.